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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 557

[Docket No. FSIS-2018-0029]

RIN 0583-AD74

Eligibility of the Socialist Republic of Vietnam to Export Siluriformes Fish and Fish Products to the United States

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Siluriformes fish inspection regulations to list the Socialist Republic of Vietnam (Vietnam) as a country eligible to export Siluriformes fish and fish products to the United States. FSIS has reviewed Vietnam's laws, regulations, and inspection system as implemented and has determined that Vietnam's Siluriformes fish inspection system is equivalent to the system that the United States has established under the Federal Meat Inspection Act (FMIA) and its implementing regulations. Under this final rule, only raw Siluriformes fish and fish products produced in certified Vietnamese establishments are eligible for export to the United States. All such products are subject to re-inspection at U.S. points-of-entry by FSIS inspectors.

DATES: *Effective Date:* [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Terri Nintemann, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On September 19, 2018, FSIS proposed to amend its regulations at 9 CFR 557.2(b)(1) to add Vietnam as a country eligible to export Siluriformes fish to the United States (83 FR 47528) (for convenience, in this final rule, "Siluriformes fish and fish products" will be shortened to "Siluriformes fish"). Although Vietnam has been allowed to export these products to the United States under the conditions described in the proposed rule (83 FR 47529), Vietnam is not currently listed in the Code of Federal Regulations (CFR) as eligible to export Siluriformes fish to the United States. FSIS proposed to add Vietnam to the regulations as eligible to export such products after the Agency conducted a documentary review of Vietnam's laws, regulations, and Siluriformes fish inspection system, as well as an in-country audit of the system, and determined that it is equivalent to the U.S. system established under the FMIA and its

implementing regulations. This final rule is consistent with the provisions of the proposed rule.

Statutory and Regulatory Basis for Final Action

As explained in the proposed rule (83 FR 45729), Siluriformes fish are an amenable species under the FMIA (21 U.S.C. 601(w)(2)). The FMIA prohibits importation into the United States of adulterated or misbranded meat and meat food products (21 U.S.C. 620). Under the FMIA and its implementing regulations, Siluriformes fish imported into the United States must be from foreign countries that maintain an inspection system that ensures compliance with requirements equivalent to all the inspection, sanitary, quality, species verification, and residue standards requirements in the United States, and all other provisions of the FMIA that are applied to official establishments in the United States. The regulatory requirements for foreign countries to become eligible to export Siluriformes fish to the United States are provided in 9 CFR 557.2, which cross-references 9 CFR 327.2, the regulations for the import of other products also subject to the FMIA.

Section 557.2(a) (cross-referencing 9 CFR 327.2(a)(1), (a)(2)(i), (a)(2)(ii)(C)-(I), (a)(2)(iii)-(iv), and (a)(3)), requires a foreign country's inspection system be authorized by legal authority that imposes requirements equivalent to those of the United States, specifically with respect to: (1) official

controls by the national government over establishment construction, facilities, and equipment; (2) direct official supervision of the preparation of product to assure that product is not adulterated or misbranded; (3) separation of establishments operations for product certified for export from product that is not certified; (4) requirements for sanitation at certified establishments and for sanitary handling of product; (5) official controls over condemned materials; (6) a Hazard Analysis Critical Control Point (HACCP) system; and (7) any other requirements found in the FMIA and its implementing regulations.

In addition to a foreign country's legal authority and regulatory requirements, the inspection program must achieve a level of public health protection equivalent to that achieved by the U.S. inspection program. Specifically, the inspection program organized and administered by the national government must impose requirements equivalent to those of the United States with respect to: (1) organizational structure and staffing, so as to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) ultimate control and supervision by the national government over the official activities of employees or licensees; (3) competent, qualified inspectors; (4) enforcement and certification; (5) administrative and technical support; (6)

inspection, sanitation, quality, species verification, and residue standards; and (7) any other inspection requirements required by the regulations in Subchapter F – Mandatory Inspection of Fish of the Order Siluriformes and Products of Such Fish, which cross-references 9 CFR 327.2(a)(2)(i).

Annually, the foreign country certifies the establishments as fully meeting the required standards and notifies FSIS about establishments that are removed from certification (9 CFR 557.2, cross-referencing 9 CFR 327.2(a)(3)).

Evaluation of Vietnam's Siluriformes Fish Inspection System

As discussed in the proposed rule (83 FR 47530), in August 2017, based on Vietnam's request, FSIS conducted a document review of Vietnam's Siluriformes fish inspection system to determine whether that system was equivalent to that of the United States. Based on its review of the submitted documentation, which included Vietnam's laws, regulations, and inspection procedures, FSIS concluded that Vietnam's inspection system is equivalent to that in the United States for raw Siluriformes fish products, specifically Siluriformes fish that fall within the FSIS product categories "Raw Product - Intact" and "Raw Product - Non-Intact." Both product categories are defined in the "FSIS Product Categorization" document, which was developed to assist foreign governments in accurately identifying the type of meat and poultry products exported to

the U.S., this document can be found on the FSIS website at:
https://www.fsis.usda.gov/shared/PDF/FSIS_Product_Categorization.pdf.

Accordingly, in May 2018, FSIS proceeded with an on-site audit of Vietnam's Siluriformes fish inspection system. The purpose of the on-site audit was to verify whether Vietnam's National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD), the central competent authority for food inspection, effectively implemented a Siluriformes fish inspection system equivalent to that of the United States. The audit of Vietnam's Siluriformes fish inspection system did not identify any deficiencies that represented an immediate threat to public health.

For more detailed information on FSIS's evaluation of Vietnam's Siluriformes fish inspection system, see the proposed rule (83 FR 47528) and for the full audit report, go to:
<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>.

Final Rule

After considering the comments received on the proposed rule, discussed below, FSIS concludes that Vietnam's Siluriformes fish inspection system is equivalent to the United States inspection system. Therefore, FSIS is amending its

Siluriformes fish inspection regulations to list Vietnam as a country eligible to export Siluriformes fish to the United States (9 CFR 557.2(b)(1)). As is stated above, under FSIS's Siluriformes fish import regulations, Vietnam must certify to FSIS that those establishments that wish to export Siluriformes fish to the United States are operating under requirements equivalent to those of the United States (9 CFR 557.2(a)).

Although a foreign country may be listed in FSIS regulations as eligible to export Siluriformes fish to the United States, the exporting country's products must also comply with all other applicable requirements of the United States. Accordingly, Siluriformes fish exported from Vietnam will continue to be subject to re-inspection by FSIS at U.S. points-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count. In addition, FSIS will continue to conduct other types of re-inspection activities, such as taking product samples for laboratory analysis to detect drug and chemical residues and pathogens, as well as to identify product species and composition. Products that pass re-inspection will be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry and within 45 days and must be exported to the country of origin, destroyed, or converted to animal food

(subject to approval of the Food and Drug Administration (FDA)), depending on the violation. The import re-inspection activities can be found on the FSIS website at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures>.

Responses to Comments

FSIS received 41 comments from fish and seafood importers, distributors, processors and wholesalers; trade associations; fish exporting companies; a domestic processor; a consumer interest group; a commercial workers union; a foreign country; a cold storage warehousing firm; and individuals. The issues raised in the comments and the Agency responses are summarized below.

The Effectiveness of Vietnam's Inspection System and Ongoing Verification of Compliance

Comment: Comments from two trade associations, the commercial workers union, the consumer interest group, the domestic processor, and an individual questioned whether Vietnam's Siluriformes fish inspection system is equivalent to that of the United States and whether Siluriformes fish processed under that system would be safe for consumption in the United States. One of the two trade associations submitted peer-reviewed articles concerning the use of antibiotics in aquaculture, citing several peer-reviewed articles.

Response: FSIS made its equivalence determination based on sound science and in accordance with U.S. international obligations. FSIS has an in-depth and rigorous equivalence process, through which it systematically determines whether a foreign country's inspection system achieves a level of public health protection equivalent to that achieved in the United States. Accordingly, the equivalence process does not require the exporting country to develop and implement the same procedures as those of the United States. Once a country is considered to have an equivalent food safety system, the FSIS equivalence process includes performing an annual records review and on-site audits at least every three years to verify whether the country's system continues to be equivalent to FSIS's system.

Regarding antibiotic residues, and as discussed above, FSIS conducts Point-of-Entry reinspection of all imported Siluriformes fish, which can include product sampling and testing for microbial, chemical and other hazards. FSIS may conduct laboratory analysis for the detection of drug and chemical residues that may have resulted from the use of drugs and pesticides, or from incidents involving environmental contaminants. FSIS analyzes imported Siluriformes fish for over 100 compounds which includes drugs, aminoglycosides, antifungal drugs, metals and pesticides. Products that pass re-inspection are stamped with the official mark of inspection and allowed to

enter U.S. commerce. If they do not meet U.S. requirements, they are refused entry into U.S. commerce and must be exported, destroyed, or converted to animal food.

On-site Audit

Comment: The commercial workers union and the consumer interest group expressed concerns over the deficiencies found during the on-site audit and the limited number of Vietnamese establishments audited. In addition, these two commenters expressed concern over the number of establishments that were delisted prior to the on-site audit.

Response: The results of the on-site audit were shared with Vietnam's Central Competent Authority (CCA). Notably, FSIS auditors did not identify any findings that represented a potential to endanger public health. The CCA has made changes to the inspection system to address the findings.

Prior to the on-site audit, Vietnam requested that FSIS remove 49 establishments from the list of 62 establishments eligible to export Siluriformes fish, because these establishments had not exported significant amounts of product to the United States. The remaining 13 exporting establishments have actively exported to the United States since FSIS assumed regulatory jurisdiction over Siluriformes fish; the others did not export a significant amount of product. FSIS' on-site audit included eight of the 13 establishments and two cold storage

facilities, which export most of the Siluriformes fish to the United States.

It is important to note that FSIS equivalence determinations are based on the foreign country's inspection system, not on an individual establishment's system. The foreign country's inspection system must ensure that establishments preparing Siluriformes fish for export to the United States comply with requirements equivalent to those of the FMIA and the supporting regulations. Vietnam's inspection system meets these requirements. The foreign country certifies the establishments as meeting the required standards and notifies FSIS about establishments that are certified or removed from certification.

Executive Orders (E.O.s) 12866 and 13563

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as a "non-significant" regulatory action under section 3(f) of E.O.

12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Expected Costs of the Final Rule

This final regulatory impact analysis updates the preliminary regulatory impact analysis by including the most recent year's (2018) trade data. This final rule is not expected to have quantified costs because it maintains the existing trade in Siluriformes fish between the United States and Vietnam. The United States has historically imported Siluriformes fish from Vietnam. Therefore, market conditions, including prices and supplies, are not expected to be impacted by this rule. From 2014 to 2018, 91.2 percent of total Siluriformes fish imports to the United States were from Vietnam, Table 1. Vietnamese Siluriformes fish accounted for 48.1 percent of U.S. consumption, Table 1.

Table 1. Summary of Siluriformes Fish Sales*

	2014	2015	2016	2017	2018	5 Year Average
	Millions of Dollars					
Total U.S. Imports¹	\$346.66	\$351.13	\$405.61	\$381.89	\$547.10	\$406.48
Total U.S. Domestic	\$351.94	\$363.61	\$385.99	\$379.71	\$360.40	\$368.33

Production²						
Total U.S. Exports¹	\$4.00	\$4.95	\$4.80	\$6.18	\$3.89	\$4.76
Total U.S. Consumption³	\$694.60	\$709.79	\$786.80	\$755.43	\$903.61	\$770.04
Total U.S. Imports from¹ Vietnam	\$309.53	\$318.40	\$367.65	\$342.96	\$514.76	\$370.66
Vietnam as % of U.S. Imports	89.3%	90.7%	90.6%	89.8%	94.1%	91.2%
Vietnam as % of U.S. Domestic Production	87.9%	87.6%	95.3%	90.3%	142.8%	100.6%
Vietnam as % of U.S. Consumption	44.6%	44.9%	46.7%	45.4%	57.0%	48.1%

Data Source: U.S. Census Bureau Trade Data

* Numbers in table may not sum to totals due to rounding

¹ Import and Export Data Accessed from USDA Foreign Agricultural Service: Global Agricultural Trade System: <https://appfas.usda.gov/gats/default.aspx/>

² U.S. Production Data Accessed from USDA National Agricultural Statistics Service: Quick Stats: https://quickstats.nass.usda.gov/results/6F6BAB14-7014-365B-ACEA-CA35C184329B?pivot=short_desc/

³ U.S. Consumption data is assumed to equal Imports + Domestic Production - Exports.

Expected Benefits of the Final Rule

This final rule may qualitatively benefit industry by maintaining market stability and continued opportunity for trade between the United States and Vietnam. Consumers in the United States will continue to have access to more choices when purchasing Siluriformes fish, specifically of the family Pangasius, which are native to Vietnam, The People's Republic of China, and other neighboring Asian nations. Pangasius have a different flavor, color and texture than other Siluriformes fish

found in the United States. The Siluriformes fish trade between the United States and Vietnam will maintain choices for consumers in the United States.¹

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), this final rule will not have a significant economic impact on a substantial number of small entities in the United States because, as stated above, the final rule will maintain existing trade.

Executive Order 13771

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), this final rule facilitates regulatory cooperation with foreign governments. Therefore, this final rule is an E.O. 13771 deregulatory action.

Paperwork Reduction Act

No new paperwork requirements are associated with this final rule. Foreign countries wanting to export Siluriformes fish to the United States are required to provide information to FSIS certifying that their inspection system provides standards equivalent to those of the United States, and that the legal authority for the system and their implementing regulations are

¹ Sea Grant Delaware Seafood Health Facts: Making Smart Choices accessed on 7/27/2018. Available at: <https://www.seafoodhealthfacts.org/description-top-commercial-seafood-items/pangasius>

equivalent to those of the United States. FSIS provided Vietnam with a questionnaire, referred to as the SRT (Self Reporting Tool), asking for detailed information about the country's inspection practices and procedures to assist the country in organizing its materials. This information collection was approved under OMB number 0583-0153. The final rule contains no other paperwork requirements.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

E-Government Act

FSIS and the U.S. Department of Agriculture (USDA) are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this

Federal Register publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe> . Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW
Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

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List of Subjects in 9 CFR Part 557

Imported products.

For the reasons set out in the preamble, FSIS amends 9 CFR part 557 as follows:

PART 557—IMPORTATION

1. The authority citation for part 557 continues to read as follows:

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§ 557.2 [Amended]

2. Section 557.2 is amended by adding "Socialist Republic of Vietnam" in alphabetical order to the list of countries at the end of paragraph (b) (1).

Done at Washington, DC:

Carmen M. Rottenberg,

Administrator.

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